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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application No.:	10/044,031
Invention:	**Purified Submucosa Graft Material**
Applicant:	Stephen F. Badylak et al.
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Examiner:	Paul B. Prebilic

Certificate Under 37 CFR 1.8(a)

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on on May 24, 2005

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RESPONSE UNDER 37 C.F.R. § 1.121

Mail Stop Interference
Commissioner for Patents
P.O. Box 1450
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Sir:

In response to the Office Action mailed on February 24, 2005 in the above-captioned application, Applicants filed a response in an attempt to comply with 37 C.F.R. § 1.607(a)(5). The submitted claims were not a listing of amended claims, but were a listing of claims under 37 C.F.R. § 1.607(a)(5). In response to the Office Action mailed on April 27, 2005, Applicants do not believe that there is a need to add status identifiers to the claims. However, a listing of the claims filed on March 25, 2005 is transmitted herewith and status identifiers have been added.

Applicants believe that no fees are required with this response. If any fees are required, the Commissioner is hereby authorized to charge any such fees or credit any overpayment to our Deposit Account No. 10-0435, with reference to our Matter No. 3220-69262.

Claims 1-20 (support in U.S. Appl. Serial No. 10/044,031)-

1. (Original) A graft prosthesis [page 3, line 6], comprising:

a purified, collagen-based matrix structure removed from a submucosa tissue source [page 3, lines 6-7], said purified structure having a contaminant level making said purified structure biocompatible [page 3, lines 7-8], said purified structure further having an endotoxin level of less than 12 endotoxin units per gram [page 3, lines 11-12].

2. (Original) The graft prosthesis of claim 1, wherein said endotoxin level is less than 10 endotoxin units per gram [page 14, line 19].

3. (Original) The graft prosthesis of claim 2, wherein said endotoxin level is less than 5 endotoxin units per gram [page 14, line 19] .

4. (Original) The graft prosthesis of claim 1, wherein said purified structure has a bioburden level of less than 2 colony forming units per gram [page 14, line 20].

5. (Original) The graft prosthesis of claim 4, wherein said bioburden level is less than 1 colony forming unit per gram [page 14, line 20].

6. (Original) The graft prosthesis of claim 5, wherein said bioburden level is less than 0.5 colony forming units per gram [page 14, line 20].

7. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source [page 4, lines 22-26; page 8, line 22].

8. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and delaminated submucosa tissue source [page 8, lines 20-24].

9. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source pretreated with an oxidizing agent to remove at least a portion of the source of endotoxin [page 9, line 22 through page 10, line 1].

10. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and then delaminated submucosa tissue source [page 8, lines 20-24].

11. (Original) A graft prosthesis [page 3, lines 9-10] comprising:

a purified, collagen-based matrix structure removed from a submucosa tissue source [page 3, lines 10-11], said purified structure having an endotoxin level of less than 12 endotoxin units per gram [page 3, lines 11-12].

12. (Original) The graft prosthesis of claim 1, wherein said purified structure is tubular (11), [page 6, line 19].

13. (Original) The graft prosthesis of claim 1, wherein said purified structure is adapted for tendon or ligament repair [page 17, line 30].

14. (Original) The graft prosthesis of claim 1, comprising multiple layers, wherein each of said layers is formed of said collagen-based matrix [page 18, lines 14-15].

15. (Original) The graft prosthesis of claim 1, wherein said purified structure is comprised of tela submucosa in strip form [page 17, line 23], said graft prosthesis comprising a plurality of said tela submucosa strips fused to one another [page 17, lines 23-24].

16. (Original) A graft prosthesis [page 3, line 6], comprising:

a purified collagen-containing matrix obtained from a mammalian tissue source [page 4, lines 11-12], said matrix comprising tela submucosa [page 4, lines 12-13] and residual contaminants from said mammalian tissue source [page 13, line 17], said matrix obtainable by a process which comprises treating said mammalian tissue to remove at least a portion of endotoxin contaminants [page 4, lines 13-14] and then removing said matrix from the treated mammalian tissue [page 4, lines 14-15], and disinfecting said matrix so that it has an endotoxin level of less than 12 endotoxin units per gram [page 3, lines 11-12; page 14, line 19].

17. (Original) The graft prosthesis of claim 16, wherein said matrix has a contaminant level making said matrix biocompatible in humans [page 7, lines 25-26; page 3, line 8].

18. (Original) The graft prosthesis of claim 16, wherein said disinfecting comprises contacting said mammalian tissue with an oxidizing agent [page 9, line 32 through page 10, line 1].

19. (Original) The graft prosthesis of claim 17, wherein said mammalian tissue source is a porcine tissue source [page 8, line 9].

20. (Original) The graft prosthesis of claim 19, wherein said porcine tissue source is porcine small intestine [page 8, line 32].

Claims 1-20 (support in U.S. Appl. Serial No. 09/798,441)-

1. (Original) A graft prosthesis [paragraph 0009, line 2], comprising:

a purified, collagen-based matrix structure removed from a submucosa tissue source [paragraph 0009, lines 3-4], said purified structure having a contaminant level making said purified structure biocompatible [paragraph 0009, lines 4-6], said purified structure further having an endotoxin level of less than 12 endotoxin units per gram [paragraph 0010, lines 5-6].

2. (Original) The graft prosthesis of claim 1, wherein said endotoxin level is less than 10 endotoxin units per gram [paragraph 0061, line 13].

3. (Original) The graft prosthesis of claim 2, wherein said endotoxin level is less than 5 endotoxin units per gram [paragraph 0061, line 13] .

4. (Original) The graft prosthesis of claim 1, wherein said purified structure has a bioburden level of less than 2 colony forming units per gram [paragraph 0061, line 14].

5. (Original) The graft prosthesis of claim 4, wherein said bioburden level is less than 1 colony forming unit per gram [paragraph 0061, line 14].

6. (Original) The graft prosthesis of claim 5, wherein said bioburden level is less than 0.5 colony forming units per gram [paragraph 0061, line 14].

7. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source [paragraph 0018, lines 9-16; paragraph 0041, lines 3-4].

8. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and delaminated submucosa tissue source [paragraph 0041, lines 1-6].

9. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source pretreated with an oxidizing agent to remove at least a portion of the source of endotoxin [paragraph 0044 and paragraph 0045, lines 1-5].

10. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and then delaminated submucosa tissue source [paragraph 0041, lines 1-6].

11. (Original) A graft prosthesis [paragraph 0010, lines 1-2] comprising:

a purified, collagen-based matrix structure removed from a submucosa tissue source [paragraph 0010, lines 3-4], said purified structure having an endotoxin level of less than 12 endotoxin units per gram [paragraph 0010, lines 4-5].

12. (Original) The graft prosthesis of claim 1, wherein said purified structure is tubular (11), [paragraph 0027, line 1].

13. (Original) The graft prosthesis of claim 1, wherein said purified structure is adapted for tendon or ligament repair [paragraph 0073, lines 3-4].

14. (Original) The graft prosthesis of claim 1, comprising multiple layers, wherein each of said layers is formed of said collagen-based matrix [paragraph 0075, lines 2-3].

15. (Original) The graft prosthesis of claim 1, wherein said purified structure is comprised of tela submucosa in strip form [paragraph 0072, line 7], said graft prosthesis comprising a plurality of said tela submucosa strips fused to one another [paragraph 0072, lines 7-8].

16. (Original) A graft prosthesis [paragraph 0009, line 2], comprising:

a purified collagen-containing matrix obtained from a mammalian tissue source [paragraph 0017, lines 1-3], said matrix comprising tela submucosa [paragraph 0017, lines 3-4] and residual contaminants from said mammalian tissue source [paragraph 0059, line 3], said matrix obtainable by a process which comprises treating said mammalian tissue to remove at least a portion of endotoxin contaminants [paragraph 0017, lines 4-5] and then removing said matrix from the treated mammalian tissue [paragraph 0017, lines 5-7], and disinfecting said matrix so that it has an endotoxin level of less than 12 endotoxin units per gram [paragraph

0010, lines 5-6; paragraph 0061, line 13].

17. (Original) The graft prosthesis of claim 16, wherein said matrix has a contaminant level making said matrix biocompatible in humans [paragraph 0036, lines 11-13; paragraph 0009, line 6].

18. (Original) The graft prosthesis of claim 16, wherein said disinfecting comprises contacting said mammalian tissue with an oxidizing agent [paragraph 0045, line 5].

19. (Original) The graft prosthesis of claim 17, wherein said mammalian tissue source is a porcine tissue source [paragraph 0039, line 7].

20. (Original) The graft prosthesis of claim 19, wherein said porcine tissue source is porcine small intestine [paragraph, 0042, line 7].

Claims 1-20 (support in U.S. Appl. Serial No. 08/916,490, now U.S. patent 6,206,931)-

1. (Original) A graft prosthesis [column 2, line 24], comprising:

a purified, collagen-based matrix structure removed from a submucosa tissue source [column 2, lines 25-26], said purified structure having a contaminant level making said purified structure biocompatible [column, lines 26-28], said purified structure further having an endotoxin level of less than 12 endotoxin units per gram [column 2, lines 32-33].

2. (Original) The graft prosthesis of claim 1, wherein said endotoxin level is less than 10 endotoxin units per gram [column 9, line 44].

3. (Original) The graft prosthesis of claim 2, wherein said endotoxin level is less than 5 endotoxin units per gram [column 9, line 44] .

4. (Original) The graft prosthesis of claim 1, wherein said purified structure has a bioburden level of less than 2 colony forming units per gram [column 9, line 45].

5. (Original) The graft prosthesis of claim 4, wherein said bioburden level is less than 1 colony forming unit per gram [column 9, line 45].

6. (Original) The graft prosthesis of claim 5, wherein said bioburden level is less than 0.5 colony forming units per gram [column 9, line 45].

7. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source [column 3, lines 20-27; column 5, line 60].

8. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and delaminated submucosa tissue source [column 5, lines 58-63].

9. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source pretreated with an oxidizing agent to remove at least a portion of the source of endotoxin [column 6, lines 35-50].

10. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and then delaminated submucosa tissue source [column 5, lines 58-63].

11. (Original) A graft prosthesis [column 2, line 30] comprising:

a purified, collagen-based matrix structure removed from a submucosa tissue source [column 2, lines 30-31], said purified structure having an endotoxin level of less than 12 endotoxin units per gram [column 2, lines 33-34].

12. (Original) The graft prosthesis of claim 1, wherein said purified structure is tubular (11), [column 4, line 38].

13. (Original) The graft prosthesis of claim 1, wherein said purified structure is adapted for tendon or ligament repair [column 11, line 56].

14. (Original) The graft prosthesis of claim 1, comprising multiple layers, wherein each of said layers is formed of said collagen-based matrix [column 12, lines 9-10].

15. (Original) The graft prosthesis of claim 1, wherein said purified structure is comprised of tela submucosa in strip form [column 11, line 48], said graft prosthesis comprising a plurality of said tela submucosa strips fused to one another [column 11, line 48-49].

16. (Original) A graft prosthesis [column 2, line 30], comprising:

a purified collagen-containing matrix obtained from a mammalian tissue source [column 3, lines 5-7], said matrix comprising tela submucosa [column 3, lines 7-8] and

residual contaminants from said mammalian tissue source [column 9, line 3], said matrix obtainable by a process which comprises treating said mammalian tissue to remove at least a portion of endotoxin contaminants [column 3, lines 8-9] and then removing said matrix from the treated mammalian tissue [column 3, lines 9-11], and disinfecting said matrix so that it has an endotoxin level of less than 12 endotoxin units per gram [column 2, lines 32-33; column 9, line 44].

17. (Original) The graft prosthesis of claim 16, wherein said matrix has a contaminant level making said matrix biocompatible in humans [column 5, lines 23-25; column 2, line 28].

18. (Original) The graft prosthesis of claim 16, wherein said disinfecting comprises contacting said mammalian tissue with an oxidizing agent [column 6, line 50].

19. (Original) The graft prosthesis of claim 17, wherein said mammalian tissue source is a porcine tissue source [column 5, line 45].

20. (Original) The graft prosthesis of claim 19, wherein said porcine tissue source is porcine small intestine [column 6, lines 6-7].

CONCLUSION

Applicants have complied with 37 C.F.R. § 1.607(a)(5) for the present application (U.S. Appl. Serial No. 10/044,031) and for priority application serial numbers 09/798,441 and 08/916,490. Although Applicants do not believe that status identifiers are required under 37 CFR 1.121, status identifiers have been added. The status identifiers are for the claims originally filed in the present application.

Respectfully submitted,

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